DRAFT FOR DISCUSSION

August 19, 2002

Concept for CBRN Full Facepiece Air Purifying Respirator Standard

(1) Goal:

Develop a NIOSH, NPPTL, tight fitting, full facepiece, air purifying respirator standard that addresses CBRN materials identified as inhalation hazards and/or possible terrorist hazards using a minimum number of filters for emergency responders.

Target: Two (2) filters

	Short Duration	**Long Duration**
Toxic Industrial Materials	**15 minutes***	**60 minutes***

*See paragraph (6)(a)(2) Gas Life.

(2) Hazards:

NIOSH has been evaluating various lists of chemicals that could be deployed as a result of a terrorist incident. In an effort to reduce the number of certification tests necessary as part of a Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) standard, efforts have been underway to categorize potential respiratory hazards into families with a representative test agents identified for each family. The following information is a synopsis of this effort to date.

The current carbon technology used in canisters and cartridges were reviewed from existing certification standards. The current standards for gas masks in Europe and the U.S. (NIOSH) were reviewed. The military purchasing specification for ASZM-T carbon for C2A1 military canisters was also reviewed. The most common parameters identified from the review of the military specification and the certification standards were the middle range certification challenges. Some of the test chemicals were considered to be redundant, since other test chemicals would guarantee the carbon effectiveness against the chemicals in question (Chlorine, Hydrogen Chloride, Hydrogen Fluoride, Arsine, CS & CN Tear Gases). Cyclohexane is the representative chemical for organic vapors. Meeting the organic vapor test for a cartridge will provide protection for all organic vapors having vapor pressures less than that of cyclohexane. From the CWA /TIC list, approximately 61 organic chemicals are cover by this logic, including GB and HD. The acid gases (32 chemicals) are covered by cyanogen chloride, hydrogen cyanide, hydrogen sulfide, and sulfur dioxide. Ammonia represents the base gases, and covers another 4 chemicals on the list. Formaldehyde, phosgene, phosphine and nitrogen dioxide are considered special case chemicals. Phosphine is a hydride and must be removed catalytically ($copper^{+2}$ and silver impregnates on carbon). Therefore, 108 of the 151 respiratory inhalation hazards can be addressed through testing these 10 chemicals. Nine of the test chemicals are listed in ITF 25.

Particulate Biological Agents and Particulate Radiological/Nuclear Agents have also been considered as part of the development of test representative agents. Thirteen biological agents are addressed as part of the standard. They include Anthrax, Brucellosis, Glanders, Pneumonic Plague, Tularemia, Q Fever, Smallpox, Venezuelan Equine

Encephalitis, Viral Hemorrhagic Fevers, T-2 Mycotoxins, Botulism, Ricin, and Staphylococcus Enterotoxin B. Sixteen radiological/nuclear agents addressed as part of the standard include Hydrogen 3, Carbon 14, Phosphorous 32, Cobalt 60, Nickel 63, Strontium 90, Technetium 99m, Iodine 131, Cesium 137, Promethium 147, Thallium 204, Radium 226, Thorium 232, Uranium 235 & 238, Plutonium 239, Americium 241. Three additional chemicals, adamsite, sodium azide, and sodium fluoroacetate, are addressed as part of the standard through particulate testing.

Chemicals		**Organization Using as Test Agent**
Ammonia		**NIOSH & EN**
Cyclohexane		**Organic Vapor - EN**
Cyanogen Chloride		**Military**
Formaldehyde		**NIOSH**
Hydrogen Cyanide		**NIOSH, EN & Military**
Hydrogen Sulfide		**NIOSH & EN**
Nitrogen Dioxide		**NIOSH & EN**
Phosgene		**Military**
Sulfur Dioxide		**NIOSH & EN**
Phosphine		**NIOSH**

(3) Respirator Use:

A. Warm Use: Less than IDLH concentrations, to REL; sustained warm zone support operations; long term use for decon, traffic control, rehabilitation, rescue and recovery; agent known & quantified.

B. Crisis Provision: Contingency use for short duration, above IDLH concentrations and high physiological (flow) demand possible; Contingency for unforeseen factors such as secondary device or pockets of entrapped hazard.

Filter	Configuration	Long Duration Less Than IDLH	Crisis Panic Demand	Short Duration Less Than IDLH
Filter #1, TIMs	Full Facepiece (Mask); Back or Chest Mounted	60 Minutes(Min)	5 Minutes	
Filter #2, TIMs	Full Facepiece Mask Mounted		5 Minutes	45 Minutes(Max)

C. The CBRN APR filter is a single use filter. After one use the filter is to be discarded.

D. CBRN respirators contaminated with liquid chemical warfare agents are to be disposed of after use.

(4) Filter Test Requirements:

Test Matrix for CBRN Air Purifying Respirators; August 19, 2002

Test Order	42 CFR Testing	Drop (not order specific)	Human Factors (not order specific)	Service Life Testing, high flow	Service Life Testing, 64 lpm flow	Particulate Testing	Penetration and Permeation Testing	Interchange-ability	LRPL Test
	3 APR systems	6 Canister Units (2 per test)	APR Systems (12 APR systems per test)	30 canister units	60 canister units	20 canister Units	6 APR systems (3 - GB and 3 - HD)	APR Systems 10 systems	25 to 29 systems
1.	Canister in Parallel Resistance Requirement 84.112	Major axis vertical, air inlet down		Service Life Testing, 100 LPM	Hot diurnal	Hot diurnal	Hot diurnal	EN 136 & EN 148 Mechanical Connector	
2.	Breathing Tube, 84.115	Major axis vertical, air inlet up	Optical Haze		Cold constant	Cold constant	Cold constant	Breathing Resistance	
3.	Facepieces; eyepieces minimum requirement 84.119	Major axis horizontal	Communications		Humidity	Humidity	Humidity	Dimensions: Size & Weight	
4.	Exhalation valve leakage test, 84.123 (2)	Gas Life Cyclo-hexane	Field of View		Transpor-tation/ vibration	Transpor-tation/ vibration	Transpor-tation/ vibration	Facepiece Leakage (mod. LRPL)	
5.	Determine CO_2 levels (4)	DOP Test 84.181	Fogging		Initial breathing resistance, 84.122	Initial breathing resistance, 84.122	System testing (GB or HD)	Field of View	
6.	Hydration (3)				Service Life Testing, 64 LPM	DOP Testing, 84.181			
7.					Final breathing resistance, 84.122	Final breathing resistance, 84.122			

Notes:

1. The six (6) APR systems may be used in the Penetration and Permeation test.
2. RCT-APR-STP-0004, Determination of Exhalation Valve Leakage Test, APR, STP, dated March 7, 2002 for HF Breathing Resistance: 3 Respirators.
3. RCT-APR-STP-0014, Determination of Leakage of Drinking Tube and Accessories for Respirator Facepieces STP, dated January 14, 2002, for HF Hydration/Drinking Tube: 3 Respirators.
4. RCT-APR-STP-0064, Determination of Facepiece Carbon Dioxide and Oxygen Concentration Levels of Tight Fitting Powered Air Purifying Respirators with the Blower Unit Off and Tight Fitting Non-Powered Gas Masks with a Tight Fitting Neck Seal STP, dated April 26, 2001 for HF CO2 Test: 3 Respirators.

	Warm Zone	Crisis[1]
	Non IDLH [2]	Greater than IDLH [2]
64 lpm flow	X	
high flow 100 lpm		X
Environmentally challenged	X	

(1) Crisis is a high use concentration at a high flow rate, 100 liters, per minute.

(2) Same test concentrations, different flow rates

(5) Special Test Requirements:

(5)(a) Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Requirement

The air purifying respirator system, including all components and accessories shall resist the permeation and penetration of distilled sulfur mustard (HD) and Sarin (GB) chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an air flow rate of 40 liters per minute (L/min), 36 respirations per minute, 1.1 liters tidal volume.

Test requirements for distilled sulfur mustard (HD) are shown in Table 1.

Table 1: Simultaneous Liquid and Vapor Challenge of APR with Distilled Sulfur Mustard (HD)

Agent	Challenge[1] Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over Minimum Service Life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (hours)
HD-Vapor	300 mg/m^3	30	40	0.30 [3]	3.0 [4]	3	12
HD-Liquid	.43 to.86 ml[2]	720					

[1] Vapor challenge concentration will start immediately after the liquid drops have been applied and the test chamber has been sealed.

[2] Liquid volume dependent on accessories used with the respirator. Minimum volume is .43 ml based on mask and single mask mounted filter/canister

[3] Three consecutive sequential test data points at or exceeding 0.3 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the test.

Test requirements for Sarin (GB) agent are shown in Table 2.

Table 2: Vapor Challenge of APR with Sarin (GB)

Challenge Agent	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough (concentration integrated over Minimum Service Life) ($mg\text{-}min/m^3$)	Number of Systems Tested	Minimum Service Life (hours)
GB	210	30 (1)	40	0.044 (3)	.75 (4)	3	12 (2)

(1) The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.

(2) The test period begins upon initial generation of vapor concentration.

(3) Three consecutive sequential test data points at or exceeding 0.044 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

(4) The cumulative Ct including all peak data points must not be exceeded for the duration of the test.

(5)(b) Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each full facepiece, air purifying respirator shall be 2000, when the APR facepiece is tested in a negative pressure mode in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers.

(6) Design Requirements:

(6)(a)(1) Filter Canister Test Challenge, Breakthrough Concentrations, and Filtration Efficiency

	Test Concentration (ppm) Draft	Breakthrough Concentration (ppm) Draft
Ammonia	2500	12.5
Cyanogen Chloride	300	2
Cyclohexane	3900	10
Formaldehyde	1000	1
Hydrogen Cyanide	940	4.7
Hydrogen Sulfide	1000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO*
Phosgene	250	1.25
Phosphine	1500	5
Sulfur Dioxide	1500	5

* Nitrogen Dioxide breakthrough is monitored for both NO_2 and NO. The breakthrough is determined by which quantity, NO_2 or NO, reaches breakthrough first.

(6)(a)(2) Gas Life: The applicant shall identify as part of the application for certification a specified rating period for the filter. Short Duration filter applications shall be identified in 15-minute intervals (15 minutes, 30 minutes, 45 minutes). Long Duration filter applications shall be identified in 30-minute intervals (60 minutes, 90 minutes, 120 minutes).

(6)(a)(3) Particulate / Aerosol filter: The filter shall be equipped with a P100 particulate filter , as described in 42 CFR, Part 84, paragraphs 84.170, 84.179, and 84.181.

(6)(b) Interchangeable consumable filter cartridges and canisters

Interchangeable consumable filter cartridges and canisters are not required as part of CBRN APR certification. Optional approval requirements for manufacturers are identified in the following paragraphs.

(6)(b)(1)(a) Mechanical Connector

The interface between the filter and the facepiece or respirator system shall use a standard thread in accordance with European Standard EN148.1. The filter shall be readily replaceable without use of special tools. The interface connector on the facepiece shall be the female thread and gasket-sealing gland as identified in EN148.1. The filter shall use a male thread in accordance with EN148.1. For respirators where the filter canister is not directly attached to the facepiece, (i.e., not mask mounted) a female thread and gasket sealing gland connector complying with EN 148.1 must be securely attached to a harness system to provide strain relief between the filter and the remaining respirator system.

(6)(b)(1)(b) Gasket Material

In addition to the requirements of EN 148.1, the gasket material shall be ethylene propylene diene monomer, EPDM, with a hardness of 65 + 10 shore A durometer at room temperature.

(6)(b)(2) Performance Requirements for Interchangeability

(6)(b)(2)(a) Breathing Resistance, Facepiece

The facepiece resistance to airflow shall be less than or equal to 10 mm water column when tested at 85 liters per minute.

(6)(b)(2)(b) Breathing Resistance, Mask Mounted (Chin Style) Filter

The filter resistance to airflow shall be less than or equal to 55 mm water column when tested at 85 liters per minute in the initial condition.

(6)(b)(2) (c) Breathing Resistance, Non-Facepiece Mounted Filter

The resistance to airflow for the respirator less facepiece shall be equal to or less than 60 mm water column height when tested at 85 liters per minute.

(6)(b)(2)(d) Dimensions and Weight, Mask Mounted (Chin Style) Filter

The maximum weight of a mask mounted (chin style) filter shall be 500 grams. The maximum size of a mask mounted (chin style) filter shall be such that the filter shall pass (with the threaded connector perpendicular to the diameter opening) through a 5-inch diameter opening.

(6)(b)(2)(e) Facepiece Leakage

A modified laboratory respiratory protection level test (LRPL) shall be performed using eight test subject, with a tariff of two (2) small, four (4) medium, and two (2) large masks. The masks shall be fitted with a test filter weighted to 500 grams and sized to the maximum permissible dimensions of (6)(b)(2)(d). The measured LRPL shall be 2000 when the APR facepiece is tested in an atmosphere containing 20-40 mg/m^3 corn aerosol of a mass median diameter of 0.4 to 0.6 micrometers.

(6)(b)(2)(f) Field of View

The field of view test shall be performed with the mask fitted with a filter sized to the maximum permissible dimensions of (6)(b)(2)(d). The requirements of (6)(d)(4) apply:

The full facepiece equipped with a single visor shall be designed so that the effective field of vision shall be not less than 70% related to the natural field of vision, and the overlapped field of vision related to the natural overlapped field of vision, shall not be less than 80%.

A full facepiece equipped with two eyepieces shall be designed so that the effective field of vision shall not be less than 70% related to the natural field of vision, and the overlapped field of vision, shall not be less than 20%.

The field of view test procedure will be developed based on procedures of EN 136.

(6)(c) Rough handling (transportability, temperature range, survivability)

Test	**Test Method**	**Test Condition**	**Duration**	**Pass / Fail Criteria** [1]
Hot Diurnal	Mil-Std-810F, 501.4	71 ^{0}C max, cyclical	3 Weeks	Gas Life, System Permeation / Penetration
Cold Constant	Mil-Std-810F, 502.4	Basic Cold, -32 ^{0}C	3 Days	Gas Life, System Permeation / Penetration
Humidity	Mil-Std-810E, 507.3	Table 507.3-II, Natural Cycle, Cycle 1	5 Days, Quick Look	Gas Life, System Permeation / Penetration
Vibration	Mil-Std-810F, 514.5	US Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours / Axis, 36 Hours Total (12,000 miles)	Gas Life, System Permeation / Penetration
Drop	3 foot drop onto concrete	Filter Only, 3 Axis	N/A	Gas Life (Cyclohexane only) DOP (2 minutes)

(1) Pass / Fail Criteria is determined after APR has been subjected to Hot, Cold, Humidity and Vibration environmental exposure sequence order. Pass / Fail Criteria for Drop test is determined after 3 drops, 1 drop per axis, is completed.

(6)(d) Operational Characteristics:

(6)(d)(1) Full Facepiece Fogging

The respirator performance rating for resistance to fogging shall be greater than or equal to 70% when tested in accordance to the fogging test procedure, Appendix A:

(6)(d)(2) Communications

The respirator performance rating for communications shall be greater than or equal to 70% when tested in accordance with the communications test procedure, Appendix B.

(6)(d)(3) Breathing Resistance

Resistance to air flow shall be measured in the facepiece of a CBRN air purifying respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute both before and after each gas service life bench test. The maximum allowable resistance to air flow is as follows:

	Chin Style	Non Facepiece Mounted
Inhalation:		
Initial	65 mm H_2O	70 mm H_2O
Final [(1)]	80 mm H_2O	85 mm H_2O
Exhalation:	20 mm H_2O	20 mm H_2O

[(1)] Measured at end of service life

(6)(d)(4) Field of View

The full facepiece equipped with a single visor shall be designed so that the effective field of vision shall be not less than 70% related to the natural field of vision, and the overlapped field of vision related to the natural overlapped field of vision, shall not be less than 80%.

A full facepiece equipped with two eyepieces shall be designed so that the effective field of vision shall not be less than 70% related to the natural field of vision, and the overlapped field of vision, shall not be less than 20%.

The field of view test procedure will be developed based on procedures of EN 136.

(6)(d)(5) Haze (Lens Abrasion)

Specimen CBRN APR facepiece lenses shall be tested for abrasion resistance and the average value of the tested specimens shall not exhibit a delta haze greater than 14%.

The applicant shall provide test data demonstrating compliance with the Haze requirement when tested in accordance with the test method described in Section 6.9, Facepiece Lens Abrasion Test, NFPA 1981, 2002 Edition.

(6)(d)(6) Carbon Dioxide

The maximum allowable average inhaled CO_2 concentration shall be less than or equal to 2%.

Test procedure RCT-APR-STP-0064 is used for carbon dioxide testing.

(6)(d)(7) Hydration

For CBRN APR respirators equipped with a hydration facility, the CBRN APR respirator shall meet all requirements of the CBRN APR standard with the hydration facility in place. In addition, dry drinking tube valves, valve seats, or seals will be subjected to a suction of 75mm water column height while in a normal operating position. Leakage between the valve and the valve seat shall not exceed 30 milliliters per minute.

Test procedure RCT-APR-STP-0014 shall be used to test the hydration facility for leakage.

(6)(e) Quality Assurance Requirements

(6)(e)(1) Quality Control Plan

Respirators submitted for CBRN air purifying respirator approval shall be accompanied by a complete quality control plan meeting the requirements of subpart E of 42 CFR, Part 84

(6)(e)(2) Sampling/Test/Inspection Plan

The applicant shall specify a sampling/test/inspection plan for respirator parts and materials to ensure the construction and performance requirements of this standard are established through the manufacturing process. As a minimum, specific attributes to be addressed are:

a. Materials of construction used for respirator parts that form a barrier between the user and ambient air.
b. Integrity of mechanical seals that comprise a barrier between the user and ambient air.
c. Final performance quality control tests on complete filter canisters demonstrating compliance with the gas life and particulate filter requirements of this standard.

(6)(e)(3) Interchangeability Inspection/Test Plans

Respirators with the interchangeability provision must include inspection/testing plans for:

a. Conformance with mechanical dimensions of respirator to filter connecting thread.
b. Conformance with mechanical dimensions of respirator to filter sealing gland including length of threads, gasket seating dimensions and configuration.
c. Conformance with material, dimensional and hardness requirements of the respirator to filter gasket

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(6)(f) Extracts from 42 CFR, Part 84

(6)(f)(1) 42 CFR, Part 84 Subparts A, B, D, E, F and G apply in total:

Subpart A: General Provisions
Subpart B: Application For Approval
Subpart D: Approval and Disapproval
Subpart E: Quality Control
Subpart F: Classification of Approved Respirators
Subpart G: General Construction and Performance

(6)(f)(2) 42 CFR, Part 84 Subpart I; the following paragraphs apply:

84.110 Gas Masks; description.
84.111 Gas masks; required components
84.112 Canisters and cartridges in parallel; resistance requirements
84.113 Canisters and cartridges; color and markings; requirements
84.114 Filters used with canisters and cartridges; location; replacement
84.115 Breathing tubes; minimum requirements
84.116 Harnesses; installation and construction; minimum requirements
84.117 Gas mask containers; minimum requirements
84.118 Half-mask facepieces, full facepieces, and mouthpieces; fit; minimum requirements
84.119 Facepieces; eyepieces; minimum requirements
84.120 Inhalation and exhalation valves; minimum requirements
84.121 Head harnesses; minimum requirements
84.123 Exhalation valve leakage test

(6)(f)(3) 42 CFR, Part 84 Subpart K; the following paragraphs apply:

84.170 Non-powered air purifying particulate respirators; description
84.179 Non-powered air purifying particulate respirators; filter identification
84.181 Non-powered air purifying particulate filter efficiency level determination

(6)(g) CBRN Draft Cautions and Limitations for Use

Not for use in atmospheres containing less than 19.5 percent oxygen.

Not for use in atmospheres immediately dangerous to life or health.

Do not exceed maximum use concentrations established by regulatory standards.

When used at maximum use concentrations the rated service time can not be exceeded. Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.

Failure to properly use and maintain this product could result in injury or death.

Follow the manufacturer's User's Instructions for changing cartridges, canisters and/or filters.

All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.

Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the applicable regulations.

Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

This respirator has been tested for operation at 21^0 C (-6^0 F). For use at low temperatures consult manufacturer's User's Instructions.

This respirator provides respiratory protection against inhalation of radiologic and nuclear dust particles only. Procedures for monitoring radiation exposure and radiation body protection must be followed.

If during use an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforseen hazard, immediately leave the area for fresh air.

Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard.

Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.

Direct contact with CBRN agents requires proper handling of the respirator after each use and between multiple entries during the same use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents, dispose of the respirator after decontamination.

The respirator should not be used beyond 12 hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation.

In an emergency situation respirators marked as approved for interchangeability may use facepieces and filters interchangeably.

Appendix A – Full Facepiece Fogging

Two individuals with a visual acuity of 20/70 better shall perform each test while wearing the apparatus according to manufacturers directions. Test participants shall be assigned a properly sized and fitted test respirator for each environmental exposure condition. All participants shall be trained in the donning and usage of the respirator per manufacturer's instructions.

Prior to testing, visual acuity shall be recorded for each subject while wearing the respirator using Snellen Eye Test charts or an equivalent method.

Test 1

The APR shall be cold soaked in an environmental chamber at minus 21°C (-6°F) for 4 hours.

At the start of each cold temperature wear trial a test participant shall enter the test chamber (maintained at -21°C) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.

The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

Visual acuity tests shall be repeated at the end of each walk period (i.e., after five minutes of walking and at the end of the 12 minute period immediately following the treadmill walk).

Test 2

The APR shall be conditioned in an environmental chamber at 15.5°C (60°F), 75% RH for 4 hours.

At the start of each cool/humid temperature wear trial a test participant shall enter the test chamber (maintained at 15.5 C) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.

The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

Visual acuity tests shall be repeated at the end of each walk period.

Interpretation of Results

Visual acuity scores obtained during each environmental test with the respirator shall be divided by a subject's visual acuity score obtained with the mask prior to testing to calculate a *performance rating* using the following equation:

$$\text{Performance Rating (\%)} = VA_{CHAMBEREX} / VA_{INITIAL} \text{ X } 100 \quad (1)$$

where $VA_{chamber\ x}$ = visual acuity score during chamber test at time x and VA_{intial} = visual acuity score obtained with the mask prior to testing.

Visual acuity performance ratings calculated from measurements taken post-donning and at the end of each treadmill walk shall be averaged for each individual subject to obtain an average visual acuity performance rating for each subject based on the environmental condition.

Average *performance rating* for each test participant shall be greater than or equal to 70% for both Test 1 and Test 2 to meet the fogging requirement.

Appendix B—Communication

1) Speech intelligibility testing shall be accomplished through the use of the Modified Rhyme Test (MRT), which evaluates a listener's ability to comprehend single words and provides an indication of speech transmission of the selected words. The MRT consists of multiple lists of 50 monosyllabic, phonetically balanced words each. A sample word list is provided in Table 1.

Table 1. Sample MRT stimulus word list

1. lick	11. same	21. pad	31. pip	41. name
2. beat	12. peal	22. din	32. seen	42. soil
3. puff	13. kit	23. sit	33. way	43. fin
4. cook	14. sat	24. win	34. west	44. cuff
5. tip	15. sin	25. teak	35. pace	45. heal
6. rave	16. gold	26. dent	36. bat	46. hark
7. hang	17. buff	27. sub	37. mop	47. heat
8. till	18. lay	28. led	38. big	48. then
9. math	19. nun	29. tot	39. tab	49. law
10. sale	20. must	30. dub	40. case	50. bean

2) Three test listeners consisting of two males and one female shall comprise the subject test panel. All participants shall be tested for "normal" hearing prior to testing by a qualified individual.

3) An additional five individuals (four males and one female) without obvious speech defects or strong regional accents shall serve as MRT speakers.

4) All participants shall be trained in the donning and usage of the respirator per manufacturer's instructions and all shall pass a qualitative facepiece-to-face fit check according to the manufacturer's instructions.

5) Procedure:

   a. The three test listeners shall be seated opposite a single test speaker for each MRT trial at a distance of 2 meters (6 ft), and they shall be facing one another. Each listener shall be given a multiple choice answer sheet or positioned before a computer and monitor that will be used to input his or her responses.

   b. Data for the MRT will be collected with a steady background noise of 60 dBA consisting of a broadband "pink" noise. A Brüel and Kjaer Type 1405 Noise Generator or equivalent will be used to produce the background noise. Background noise levels will be monitored at a position near the listening panel using a Type 2 digital sound level meter and recorded at the beginning, middle, and end of each MRT session.

c. The test speaker shall present each stimulus word using the carrier phrase "The word is _____."

d. Speakers will be instructed and trained to maintain a constant output volume at 75 dBA to 85 dBA for all presented words. A Type 2 digital sound level meter will be positioned in front of the speaker within his or her sight to provide feedback concerning the loudness of their voice during testing. Speaker output levels will be recorded at the beginning, middle, and end of each MRT session for verification.

e. Listeners will select the word that was perceived to be spoken from a list of six response words presented on the computer monitor by clicking a button on the monitor that corresponds to the perceived word. If given a paper answer form, subjects will circle their selection. A sample answer sheet is provided in Figure 1.

f. Test listeners shall then provide a thumbs-up hand signal to the speaker to cue him or her to say the next word.

g. An individual speaker will present a total of 50 stimulus words to complete one MRT trial. A different speaker shall then be used to present the next MRT trial. Test speakers will continue to rotate among the speaker test panel until all trials have been complete. A sample test matrix is provided in Table 2.

h. Data will be obtained without the respirator and with the respirator worn and operated per the manufacturer's instructions by both speakers and listeners. All conditions shall be randomly assigned and a different word list shall be used for each test. Again, an example of a test matrix is provided in Table 2.

Table 2. Sample MRT test matrix

Speaker	Speaker Condition	Listeners' Condition	Word list
1	No mask	No mask	1
2	No mask	No mask	3
3	Masked	Masked	5
4	Masked	Masked	7
5	No mask	No mask	9
2	Masked	Masked	2
4	No mask	No mask	4
1	Masked	Masked	6
5	Masked	Masked	8
3	No mask	No mask	10

i. A total of 10 MRT trials shall be performed. The 10 trials will result in a total of 15 MRT scores (five per listener) for the unworn mask condition and 15 scores for the worn condition.

j. Listener performance on the MRT shall be scored in terms of the percentage of words correctly identified using the equation:

$$\% \text{ correct} = (\text{number correct} - (\text{number incorrect}/5)) * 2 \qquad (1)$$

The equation accounts for chance or guessing made possible by the multiple-choice form of the answer sheet (*Human Engineering Guide to Equipment Design,* American Institutes for Research, Washington, DC, 1972).

k. Individual listeners' scores for the unworn and worn respirator conditions shall be averaged for each condition.

l. Each individual listener's average score with the respirator shall be divided by their average unmasked MRT score to calculate a *performance rating* (ref equation (2)). (Because the listening subjects serve as their own controls, the performance rating allows the effect of the respirator condition to be isolated from the effect of the individual).

$$\text{Performance rating } (\%) = \left(\frac{\text{MRT \%correct with respirator}}{\text{MRT \%correct without respirator}} \right) \text{x } 100 \qquad (2)$$

m. The communications requirement shall be met if the average *performance rating* is greater than or equal to 70%.

MRT Listener Response Sheet Date: _____ Listener Position: _____ TP#: _____

Scenario: _____ Speaker: TP#: _____ Mask Condition: _____

** 1-A **

1	kick	lick	sick	14	sack	sad	sap	27	sup	sub	sud	40	cake	came	cave
	tick	wick	pick		sag	sat	sass		sum	sun	sung		cane	case	cape
2	neat	beat	seat	15	sit	sip	sill	28	wed	fed	bed	41	tame	came	fame
	meat	feat	heat		sick	sin	sing		led	shed	red		same	name	game
3	pun	puff	pup	16	fold	sold	gold	29	pot	hot	lot	42	toil	boil	foil
	pub	pus	puck		hold	cold	told		not	tot	got		coil	oil	soil
4	hook	shook	book	17	but	bug	bus	30	duck	dud	dung	43	fig	fizz	fit
	took	cook	look		buff	bun	buck		dun	dug	dub		fib	fin	fill
5	lip	hip	dip	18	late	lake	lay	31	pit	pin	pig	44	cuss	cud	cup
	sip	rip	tip		lame	lane	lace		pill	pick	pip		cut	cub	cuff
6	rake	rate	ray	19	run	bun	fun	32	seethe	seek	seen	45	heel	peel	keel
	raze	race	rave		sun	nun	gun		seed	seep	seem		feel	eel	reel
7	fang	bang	hang	20	dust	gust	must	33	say	pay	may	46	mark	bark	dark
	sang	gang	rang		bust	just	rust		gay	way	day		lark	hark	park
8	will	hill	kill	21	path	pack	pass	34	best	west	nest	47	heath	heave	heap
	bill	fill	till		pat	pad	pan		vest	test	rest		heat	heal	hear
9	map	mat	math	22	dip	dim	din	35	page	pane	pace	48	then	den	ten
	mad	mass	man		dill	did	dig		pave	pale	pay		pen	hen	men
10	pale	sale	bale	23	fit	hit	bit	36	bash	bat	ban	49	law	saw	paw
	gale	male	tale		sit	kit	wit		back	bath	bad		jaw	raw	thaw
11	sane	sake	safe	24	tin	fin	sin	37	hop	cop	shop	50	beat	beak	beach
	save	same	sale		win	pin	din		mop	pop	top		beam	bean	bead
12	peak	peach	peas	25	tear	teal	teak	38	dig	wig	big				
	peal	peace	peat		team	tease	teach		fig	pig	rig		**Score**		
13	kin	kid	kick	26	dent	tent	rent	39	tack	tan	tab				
	king	kit	kill		went	sent	bent		tang	tam	tap				